

Remarks

After entry of the amendment, claims 162-239 are pending.

The specification has been amended to up-date the related applications.

Claim 192 has been amended to change "consisting essentially of" to --comprising--.

New claim 239 is supported by the specification.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Prior Art Rejections

Claims 162-169, 171-185, 189-197, 201-211, 213-227 and 231-238 are rejected under 35 USC § 102(b) as being anticipated by Curtet et al (U.S. Patent No. 4,895,726).

Claims 170, 186-188, 198-200, 212 and 228-230 are rejected under 35 USC § 103 as being obvious over Curtet et al (U.S. Patent No. 4,895,726) alone or in view of Klimesch et al (US Patent No. 4,895,726).

Applicants respectfully traverse the rejection and respectfully submit that Curtet does disclose or suggest the presently claimed carrier particles coated with an admixture comprising at least one polymer and fenofibrate.

At column 2, lines 5-20,¹ Curtet teaches:

- (1) co-micronizing fenofibrate and sodium lauryl sulfate (i.e., surfactant);
- (2) adding lactose (i.e., carrier particles) and starch to the mixture obtained in (1);
- (3) converting (2) to granules in the presence of water;
- (4) drying and grading the granules;
- (5) adding polyvinylpyrrolidone (i.e., polymer) and magnesium stearate to the graded granules; and
- (6) filling gelatin capsules with the mixture obtained from (5).

Curtet teaches adding lactose (carrier particles) to co-micronized fenofibrate/surfactant to form granules in the presence of water. Thereafter, polyvinylpyrrolidone (polymer) is added to the granules.

Curtet's process would not produce carrier particles coated with an admixture comprising at least one polymer and fenofibrate. Moreover, Curtet does not provide any motivation or

suggestion for one skilled in the art to coat carrier particles with an admixture comprising at least one polymer and fenofibrate.

Because the process described by Curtet cannot produce carrier particles coated with an admixture comprising at least one polymer and fenofibrate, Curtet cannot anticipate the claimed invention. Because Curtet does not provide any motivation or suggestion to produce carrier particles coated with an admixture comprising at least one polymer and fenofibrate, Curtet, by itself, cannot render the presently claimed invention obvious.

Applicants respectfully submit that Klimesch does not cure the deficiencies of Curtet. Klimesch is directed to processes for preparing solid pharmaceutical forms by extruding a polymer melt containing the active ingredient.² The process described by Curtet does not use an extrusion process and does not use a polymer melt. There is no motivation to modify the process described by Curtet based on the teachings of the wholly unrelated and significantly different process described by Klimesch.

MPEP 2141.03 which states (emphasis in original):

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

Applicants respectfully submit that it is improper to look to isolated teachings in Klimesch without looking to Klimesch in its entirety, e.g., that Klimesch teaches processes that require melting polymer compositions. Such a process is unrelated to the process described by Curtet, and there is no motivation or suggestion to modify the process described by Curtet to include a melting step. The selection of isolated teachings from Klimesch amounts to a hindsight finding of obviousness, which is not permitted under § 103 or MPEP 2141.03. Moreover, there is no motivation or suggestion to select fenofibrate from the laundry list of drugs described in Klimesch at columns 5-6.

In view of the above, Applicants respectfully submit that Curtet alone and in combination with Klimesch does not disclose or suggest the presently claimed invention, and respectfully request that the rejections under §§ 102(b) and 103 be withdrawn.

¹ See also Curtet at column 2, lines 40-53.

² Klimesch at column 3, lines 24-29; claim 1.

Information Disclosure Statement

Applicants are filing an Information Disclosure Statement concurrently herewith. Applicants respectfully request that the Examiner consider the information cited in the Information Disclosure Statement and PTO-1449 Form, and please provide Applicants with an initialed copy of the PTO-1449 Form with the next communication from the Office.

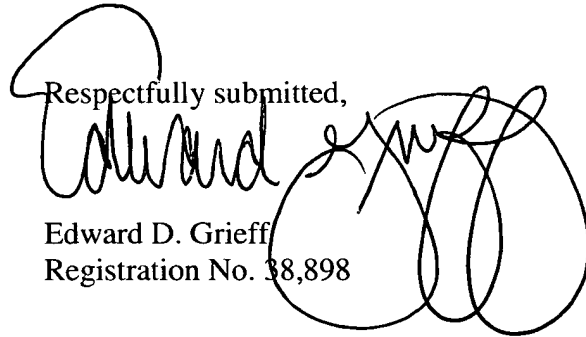
Terminal Disclaimer

Applicants are filing a Terminal Disclaimer in view of US Patent No. 6,652,881 and co-pending US Application No. 10/290,333.

Conclusion

An early and favorable reconsideration and allowance of claims 162-239 is respectfully requested. Examiner Sheikh is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over the typed name and registration number.

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